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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/707,003	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Sequence Rule Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

CFR §1.821(d) reads as follows:

> Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims or the patent application.

Figures 12A, 13A, and 14A of the instant application contain nucleic acid sequences which are not preceded by "SEQ ID NO:". It is noted that the instant specification makes reference to the nucleic acid sequences depicted in Figures 12A, 13A, and 14A by use of EST numbers instead of SEQ ID NOs. Applicant is reminded that either the brief description of drawings for the above Figures or Figures themselves should make a reference to the sequences by use of the sequence identifiers in accordance with CFR §1.821(d). Note that EST numbers are not acceptable forms of sequence identifiers. Further, the sequences in Figures 12A, 13A, and 14A should be entered in the sequence listing as well as CRF, if they have not been entered. It is also noted that primer sequences listed in paragraph 150 of the instant specification are not

preceded by SEQ ID NOs. Applicant is encouraged to review the entire application to ensure sequence rule compliance with the requirements of 37 CFR 1.821 through 1.825. Any response to this action must correct this deficiency, as this requirement will not be held in abeyance.

Response to Arguments/Election/Restrictions

Applicant's election with traverse of SEQ ID NO:863 in the reply filed on August 16, 2006 is acknowledged. The traversal is on the ground(s) that all nucleic acid sequences identified as SEQ ID NOs:861-863 are related by genomic location. This is not found persuasive because the nucleic acid sequences of SEQ ID NOs:861-863 are distinct in material design due to the distinct and non-overlapping nucleotides that comprise SEQ ID NOs:861-863. By virtue of the distinct nucleic acid sequences, one SEQ ID NO is not an obvious variant of another SEQ ID NO. Accordingly, all three nucleic acid sequences are distinct and independent inventions.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1-20 have been cancelled, and claims 21-31 have been added. SEQ ID NOs:861 and 862 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Accordingly, claims 21-31 pertaining to SEQ ID NO:863 are under examination.

Specification

The disclosure is objected to because of the following informalities: The title of the instant application as well as the abstract contain the term, "novel". The title as well as the abstract of a patent application should be descriptive of the claimed subject matter, which is presumed to be novel. See M.P.E.P. §606. Accordingly, the term "novel" is not descriptive of the claimed subject matter in the instant case because it is obvious that claimed invention be novel.

Appropriate correction is required.

The disclosure is objected for containing sequence non-compliance subject matter in Figures 12A, 13A, and 14A and at least paragraph 150 in the specification. See Notice to Comply.

Further, applicant is hereby notified that the lengthy specification consisting of 54,038 pages has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. See MPEP §608.01.

Claim Objections

Claims 21-23 are objected to for containing non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claim, claim 21 recites "(c) a sequence at least 62/87 identical to (a) or (b)" in line 5. Since the instant specification consists of 54,038 pages, it imposes serious unduly burden on the examiner to search for the definition imparted by the "62/87". Further, given the broadest reasonable interpretation of the "62/87", it appears to indicate a ratio between two different oligonucleotides. However, it still remains unknown to the examiner what constitutes "62/87" as claimed in the instant application, rendering claims 21-31 indefinite.

Moreover, claim 27 recites "15/21" in line 1.

Applicant is hereby advised to amend the claims or to point out the particulars in support of the applicant's own definition imparted by "62/87" and "15/21".

Further, it is unclear and ambiguous how SEQ ID NO:863 consisting of 87 nucleotides can consist of an isolated nucleic acid consisting of 18 to 120 nucleotides, as claimed in claim 23. Since the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim, the maximum number of nucleotides consisting of the nucleic acid of claim 23 must not exceed 87 nucleotides. See *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931) and *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948). Since the nucleic acid of claim 23 is drawn to up to 120 nucleotides in length, claim 23 is internally inconsistent.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'." (Wands, 8 USPQ2d 1404). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Due to the voluminous nature of the instant specification containing 54,038 pages, the examiner is precluded from examining the content of the instant specification to the extent of

working examples pertaining to the claimed subject matter in claims 30-31. In order to show that the specification enables one skilled in the art to make/use the claimed invention without undue experimentation, it must provide working examples and direction/guidance with regard to the gene expression inhibition system comprising the nucleic acid of SEQ ID NO:863 (claim 30) and the gene expression detection system that selectively detects expression of at least one gene comprising the nucleic acid of SEQ ID NO:863 (claim 31). Although the claims are not drawn to methods, they read on both *in vivo* and *in vitro* use of the recited systems. Therefore, in order to be fully enabled for the claimed invention, the instant specification needs to provide exemplifications of the recited systems *in vivo* and *in vitro*.

If applicant believes that the instantly claimed invention is enabled either fully or in scope, applicant is required to point out the particulars in response to this Office action, accompanied by the specific page and/or paragraph numbers.

In the absence of such examples/guidance/direction provided by the specification, the instantly claimed invention is considered to have failed to comply with the enablement requirement.

Conclusion

No claim is allowed.

Of note on the record, SEQ ID NO:863 appears to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

TC 1600

JANE ZARA, PH.D.
PRIMARY EXAMINER

Application No.: 10/707,003

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 37 CFR §1.821(g). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. §§1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. §§1.821-1.825. Applicants attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a Sequence Listing as required by 37 C.F.R. §1.821(c).
- [ ] 3. A copy of the Sequence Listing in computer readable form has not been submitted as required by 37 C.F.R. §1.821(e).
- [ ] 4. A copy of the Sequence Listing in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. §1.822 and/or 1.823, as indicated on the attached copy of the marked-up Raw Sequence Listing.
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. §1.825(d).
- [ ] 6. The paper copy of the Sequence Listing is not the same as the computer readable from of the Sequence Listing as required by 37 C.F.R. §1.821(e).
- [ ] 7. Other:

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the Sequence Listing. (If the unidentified sequences are not provided on the CRF)
- [X] An initial or substitute paper copy of the Sequence Listing, as well as an amendment directing its entry into the specification. (If the unidentified sequences are not provided in the paper copy)
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). (If a new paper and/or CRF are required)

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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